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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/591,561

Applicant(s)

WAX ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. To simplify the restriction, which is a method for treating a subject with glaucoma comprising administration of an agent which antagonizes, inhibits, inactivates, reduces, suppresses, and/or limits the release, synthesis or production of TNF- α , classified in class 514, subclass 2, the agents or methods used in the treatment will be listed in the Groups below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. recombinant TNF- α soluble receptor
- II. etanercept
- III. thalidomide
- IV. rolipram or phosphodiesterase 4 inhibitor
- V. anti-TNF- α antibody
- VI. monoclonal or polyclonal antibody
- VII. infliximab
- VIII. hydrazine sulfate
- IX. pentoxifylline,
- X. ketotifen
- XI. tenidap
- XII. vesnarine
- XIII. cyclosporine
- XIV. peptide T

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- XV. sulfasalazine
- XVI. thorazine
- XVII. antioxidants
- XVIII. corticosteroids
- XIX. marijuana
- XX. glycyrrhizin
- XXI. sho-saiko-to
- XXII. L-carnitine
- XXIII. hyperthermia
- XXIV. hyperbaric oxygen therapy

The inventions are distinct, each from the other because of the following reasons:

2. Restriction is deemed proper because the methods constitute patentably distinct inventions for the following reasons. Inventions are different methods because they require different agents or processes, different modes of administration and have different effects. The different groups require different searches and consideration for patentability, and each mode of treatment requires an agent and/or method of administration that is not required by any of the other groups. Thus, although all the methods are directed to treatment of glaucoma by administration an agent (such as marijuana) or a process (hyperbaric oxygen therapy), that somehow affects $\text{TNF-}\alpha$, they are all patentably distinct inventions, because each treatment is with either a patentably distinct compound or method, all of which have different actions and effects.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that this is not a species election. In order to be fully responsive, Applicant must select one invention from Groups I-XXIV, and the reply must also identify the claims readable on the elected Group, including any claims subsequently added.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

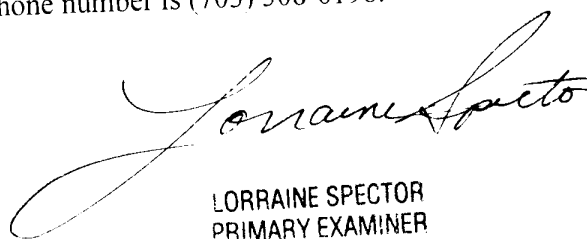
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR
PRIMARY EXAMINER